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Dockets Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Room 1061

Rockville, MD 20852

Subject: **Docket No. 99D-0557** **URGENT**
Xenotransplantation

cc: **Dr. Michael Friedman**
Lead Deputy Commissioner, FDA
via fax

We urge you to include other nonhuman animal species, besides primates, in the FDA's de facto ban on live organ, cell, and tissue transplants at least for the following reasons:

- 1) Pigs are not any safer than nonhuman primates: witness swine influenza, the Porcine Endogenous Retroviruses (PERVs), the Australian paramyxovirus; a novel strain of Hepatitis E, found in US pig herds, and the new Malaysian "Nipah" virus that has devastated humans and pigs alike. (The influenza virus of 1918, which resembled a common swine flu, killed more people in modern history than any other epidemic including AIDS and the Black Plague; and PERVs, present throughout the pig genome, have infected human cells in vitro.)
- 2) FDA has violated the national Environmental Policy Act by failing to perform an environmental impact statement before allowing clinical xenotransplantation experiments.
- 3) We strongly oppose our tax dollars being used to develop xenotransplantation. How can such a hazardous experiment be receiving substantial public and private financing, without adequate public debate, when it has a direct bearing on public health and safety and is *irreversible*?
- 4) There are safer, more cost-effective, and humane alternatives to xenotransplantation that are not being explored by regulatory authorities. These include investing heavily in preventive medicine programs to reduce the need for transplants of all kinds, and increasing the pool of human organs, as many European countries have successfully done through legislative programs.

Please respond to the following questions that reflect our valid concerns about xenotransplantation:

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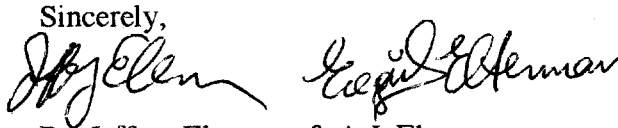
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- 1) Who will be held accountable if a zoonotic virus spreads to the human population?
- 2) Who will pay the hidden costs of breeding, housing, feeding, medicating, screening, transporting, rendering, and disposing of the waste and remains of herds of transgenic pigs?
- 3) Given that over 45 million Americans lack basic health care, can we spend hundreds of thousands of dollars on operations that promise to be more expensive than standard allotransplants?
- 4) Can we justify raising more pigs for human use at a time when the Environmental Protection Agency is placing new restrictions on livestock pollution?
- 5) Xenograft recipients and their close contacts would require life-long monitoring for signs of infection: the FDA wants to establish a multi-million dollar registry and archive to house blood and tissue from source animals and patients for at least 50 years, at taxpayer expense. Is this fair?
- 6) Why did an April 1998 General Accounting Office report on organ donation reveal an untapped donor pool of 150,000 people annually when our government claims it is doing all it can to increase organ donation?
- 7) Why do European countries like Austria, Belgium, and Spain have much higher organ donation rates than the United States?
- 8) Given the acknowledged danger xenotransplantation poses to individual patients and society at large, does this technology deserve continued public support?

We trust that you will not engage in a major public health experimentation at the public's expense without accountability. Such an experimentation with public safety should not be allowed with private funds either, for the same reasons. We look forward to your response.

Sincerely,

Dr. Jeffrey Elterman & A.J. Elterman

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